

Evaluation of CACLD's Proposed Revisions to the Regulations

The California Association of Crime Laboratory Directors (CACLD) has proposed revisions to the Department of Health Services' Title 17 regulations pertaining to forensic and breath alcohol analysis. The following is the Food and Drug Laboratory Branch, Forensic Alcohol Program's overall evaluation of the proposed revisions. A copy of CACLD's proposed regulations with more specific endnotes describing the program's concerns and recommendations is included as a separate document.

Forensic Alcohol Analysis

CACLD's proposed revisions to the Department's regulations governing the operation of forensic alcohol analysis laboratories represent a significant reduction in the current technical and scientific requirements imposed on the laboratories. Virtually every aspect of the current regulatory program would be reduced: personnel qualifications, method standard of performance and procedure, proficiency testing, and site inspections.

Personnel Qualifications

The current regulations require the Department to qualify laboratory personnel. The Department evaluates the education [§§1216.1.(e)(1), 1216.1.(f)(1)], training [§§1216.1.(f), (2) and (3)], and experience [§1216.1.(e)(2)] of the staff nominated by the laboratories. Candidates are then required to successfully complete a proficiency test and written examination conducted by the Department [§§1216.1.(e)(3), 1216.1.(f)(4)]. The current regulations require that forensic alcohol analysis shall only be performed by persons qualified by the Department [§1216.1.(a)(1)].

The regulations proposed by CACLD (see proposed Section 1216.2) would not only eliminate the Department's authority to qualify personnel to perform forensic alcohol analysis, but also significantly reduce the requirements for such qualification. There would be no specific requirements for training or experience. Each individual laboratory would be free to set its own standards here. While the educational requirements for the entry-level analyst category are actually increased (baccalaureate degree in any natural science vs. 60 units college level training), the requirements for coursework in chemistry are reduced. Perhaps most importantly, the proposed regulations do not require staff to demonstrate competency based on the completion of an external proficiency test and written examination.

CACLD's proposed regulations also do not establish any separate requirements for a supervisory classification. Under the current regulations a forensic alcohol supervisor is a person who can be responsible for all aspects of the performance of forensic alcohol analysis [§1215.1.(f)]. Generally, the supervisor writes the methods, interprets the analytical results, directs corrective action for quality control failures, and supervises the personnel who perform the analyses. Consistent with these responsibilities, the supervisor is currently required to have a higher degree of knowledge and experience. The Department requires the supervisor have a higher level of education (baccalaureate or higher degree in chemistry, biochemistry, or other appropriate discipline as determined by the Department) and experience (two years of experience in performing forensic alcohol analysis or satisfactorily completion of specialized training approved). Again, CACLD proposes no special requirements for persons responsible for the management and supervision of forensic alcohol analysis.

Method Standards of Performance and Procedure

The regulations set standards of performance for the methods used for forensic alcohol analysis. (accuracy and precision, non-interference of anticoagulants/preservatives added to the sample, and results obtained for alcohol free subjects). Under the current regulatory program, the Department defines these requirements and sets forth procedures for experimentally demonstrating that the method meets required standards of performance. This establishes an important level of accountability. Under the regulations proposed by CACLD, laboratories would evaluate their own methods and determine whether they meet the required standards of performance.

The current regulations set standards of procedure for the methods used for forensic alcohol analysis. These regulations are for the most part retained. However, CACLD has proposed eliminating the requirement that laboratories independently establish the concentration of the alcohol standards used to calibrate a method and instead be permitted to use commercial standards whose concentrations were determined by the vendor. Moreover, the current regulations authorize the Department to inspect a laboratory's methods and other records in order to determine whether the laboratory's procedures meet the requirements of the regulations. This authority is eliminated in the regulations proposed by CACLD, and the laboratories would evaluate their own procedures to determine compliance.

Proficiency Testing

The current regulations require each laboratory to demonstrate satisfactory performance in a proficiency testing program operated by the Department [§1216.1.(a)(3)]. The Department conducts three proficiency tests per year. Laboratories with more than one method of analysis are sent sets of test samples for each method. The laboratory results are scored on a scientific basis. The Department uses the proficiency test results to evaluate the accuracy of the forensic alcohol analyses performed by the laboratory, and the results must meet the requirements of the regulations [§1217.7.(b)]. Laboratories with unsatisfactory performances are directed by the Department to take specific corrective actions. These laboratories must file a written report of the corrective action taken and submit experimental data demonstrating that the method again meets the required standard of performance.

Under the regulations proposed by CACLD [see proposed Section 1216.1.(b)], laboratories are required to demonstrate "satisfactory performance" in a proficiency testing program that follows ASCLD-LAB guidelines and uses an ASCLD-LAB approved proficiency test provider. According to the ASCLD/LAB guidelines, a laboratory is required to participate in only one proficiency test per year. For laboratories with multiple methods, there is no requirement that each method be tested. The requirement in the proposed regulations that laboratories demonstrate "satisfactory performance" actually exceeds the requirements of the law. (H&S Code §100702 only requires the laboratories to "participate" in a proficiency test). Moreover, "satisfactory performance" is not defined in the proposed regulations and according to ASCLD/LAB guidelines, "successful completion" of a proficiency test shall mean either obtaining the correct response on the proficiency test or taking corrective actions in accordance with laboratory policy.

The proposed regulations do not describe the response to be taken in case of an unsatisfactory performance by a laboratory. The requirements are actually spelled out in greater detail in the law. H&S Code §100702(d) requires each individual laboratory to have a written procedure describing its review of proficiency test results and the corrective action taken when proficiency test results are “inconsistent” with expected test results. In other words, under the law and regulations proposed here, each laboratory would be authorized to evaluate its own performance on a proficiency test and determine whether such performance was satisfactory.

Site Inspections

The current regulations require each laboratory to be periodically site inspected by the Department [§1216.1.(a)(4)] and the results must meet the requirements of the regulations [§1217.7.(a)]. The Department is authorized to enter a laboratory at all reasonable times to conduct such inspections [§1217.6.(b)].

Under the regulations proposed by CACLD, there would no requirements for any site inspections of the laboratories.

Breath Alcohol Analysis

CACLD’s proposed revisions to the Department’s regulations pertaining to breath alcohol analysis represent a dramatic reduction in the current technical and scientific oversight of breath testing in California. CACLD’s proposed revisions are apparently intended to even eliminate the requirement that breath testing be performed under any governmental jurisdiction at all. The current regulations [§1221.1.(b)(1)] require that breath alcohol analysis shall be under the direct jurisdiction of a governmental agency or licensed forensic alcohol laboratory. This requirement is eliminated with CACLD’s proposed revisions.

The current regulations place responsibility for the direct oversight of breath alcohol analysis on the forensic alcohol laboratories. The laboratories are responsible for periodically determining the accuracy of the breath instruments [§1221.4(a)(2)]. The laboratories provide the reference samples of known alcohol concentration used to test the instruments [§1221.4(a)(2)(A)]. While regular qualified operators may perform the periodic analyses, a laboratory must interpret the results to determine whether the instruments continue to meet the accuracy requirements [§1221.4.(a)(2)(A)1)]. The laboratory must maintain records showing the frequency of such analyses and the person performing the analyses [§1221.4(a)(6)].

All of these specific requirements are eliminated or significantly reduced with the revisions to the regulations proposed by CACLD. The proposed regulations do not specify who supplies the reference samples of known alcohol concentration used to periodically check the breath instruments. The proposed regulations do not specify who interprets the results of the periodic analyses. There would be no specific requirements regarding what accuracy test records are maintained.

The proposed revisions would also significantly reduce the level of laboratory oversight of the training of instrument operators. While the current regulations require this training to be supervised by qualified laboratory staff [§1221.4.(a)(4)], the language proposed by CACLD, would substitute the more general requirement that the laboratory supervise this training. The proposed regulations also add the vague

language, "Training may include the use of multimedia presentations, secondary trainers, and/or other methods, as approved by the laboratory." Moreover, CACLD has proposed an amendment [see proposed Section 12220.2(a)(4)] to the record keeping requirements imposed on law enforcement agencies stating that these agencies shall maintain records of operators trained by the agency. This language suggests that law enforcement agencies would be permitted to train their operators independent of any oversight by the forensic alcohol laboratory. Similar new language has been added to require law enforcement agencies to maintain records of all maintenance performed on each instrument suggesting that such maintenance may be performed by the agency independent of any oversight by the forensic alcohol laboratory amendment [see proposed Section 12220.2(a)(3)].

Virtually every state operates a program in which a state-level agency provides overall technical and scientific oversight of breath alcohol analysis. In California, the Department of Health Services is the designated agency. However, the Department does not provide this oversight directly. Instead, the Department has historically relied on a partnership with the licensed forensic alcohol laboratories. The laboratories maintained and periodically determined the accuracy of the instruments and trained the operators employing procedures approved by the Department. The revisions to the regulations proposed by CACLD would not only eliminate the Department's oversight of the forensic alcohol laboratories, but also significantly reduce the laboratories' role in directly overseeing breath testing performed by law enforcement.